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09/915,706	07/26/2001	David R. Nelson	5112	9372

7590 09/22/2003
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EXAMINER

GRASER, JENNIFER E

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/22/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/915,706

Applicant(s)

Nelson

Examiner

Jennifer Graser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Amendment A, 7/24/03
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-9, 13-21, 25-28, and 30 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-9, 13-21, 25-28, and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Acknowledgment and entry of the Amendment submitted 3/19/03, Paper No. 12A is made. Claims 3-9, 13-21, 25-28 and 30 are currently under examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3-9, 13-21, 25-28 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is vague and indefinite because it is unclear whether Applicants intend for the mutation to occur within nucleotides 1218-2610 of SEQ ID NO:1 or somewhere else within the gene. SEQ ID NO:1 is 3588 nucleotides long. The claim recites that the *V.anguillarum* strain 'comprises a *mugA* gene comprising nucleotides 1281-2610 of SEQ ID NO:1 the *mugA* gene being mutated". The term "comprising" is open language and allows for much more, i.e, the full-length gene. If the claim is intended to recite that the mutation is located within nucleotides 1281-2610 of SEQ ID NO:1, then the claim should be amended to recite "A live, attenuated strain of *V.anguillarum* which comprises a mutated *mugA* gene comprising nucleotides 1281-

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2610 of SEQ ID NO:1, wherein said mutation is located within nucleotides 1281-2610 of SEQ ID NO:1 and renders the strain incapable of expressing a functional *mugA* protein.” provided that there is written support in the specification for this language.

Claims 8, 16 and 28 are also vague and indefinite because it is unclear whether or not Applicants intend for the mutation to occur within nucleotides 1218-2610 of SEQ ID NO:1 or somewhere else within the gene. SEQ ID NO:1 is 3588 nucleotides long. The term “comprises” is open language and allows for much more, i.e, the full-length gene. If the claim is intended to recite that the mutation is located within nucleotides 1281-2610 of SEQ ID NO:1, then the claim should be amended as indicated above.

New claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The specification teaches that a gene responsible for helping the bacterium *V.anguillarum* to grow in fish mucous has been identified and that mutating this gene so that it renders the bacterium incapable of growing in mucous creates a successful live vaccine. However, claim 30 fails to mention this gene and fails to describe the location of the mutation. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. The novel inventive concept appears to be the discovery of the *mugA* gene and mutating it to render a

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strain incapable of growing in salmon intestinal mucous. Claim 30 allows for strains with intact *mugA* genes and different mutations which render the bacterium incapable of functioning properly or for bacterium with loss of pili, etc.. Clarification is requested.

Claim Rejections - 35 USC § 112-New matter

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 3-9, 13-21, 25-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 3-9, 16-21, and 25-28 have been amended to recite "...a live, attenuated strain of *V.anguillarum* which comprises a *mugA* gene comprising nucleotides 1281-2610 of SEQ ID NO:1, the *mugA* gene being mutated such that the strain is incapable of expressing a functional *mugA* protein". The amendment on page 10 recites that support for this limitation can be found in the specification on page 14, lines 10-21. A review of page 14, lines 10-20, did not reveal this language. There is no mention of nucleotides 1281-2610. Additionally, as stated above it is unclear whether nucleotides 1281-2610 is the location of the mutation or something else. The current claims allow for the mutation to occur outside of the range of nucleotides 1281-2610 due to the open term "comprising", i.e., somewhere else within the 3588 nucleotides of SEQ ID

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NO:1. Applicants must point to specific support for this new limitation or remove it from the claims.

Claim Rejections - 35 USC §112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 30 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ‘a mutated strain of *V.anguillarum* wherein said mutation is located within nucleotides X-Y of SEQ ID NO:1 and renders the strain incapable of growing in salmon intestinal mucous (or incapable of expressing a functional *mugA* protein)’, does not reasonably provide enablement for ‘any mutated strain of *V.anguillarum* characterized in that the strain is incapable of growing in salmon intestinal mucous’. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant specification teaches that a live, attenuated mutant designated M93Sm D contains an insertion in the *mugA* gene represented by SEQ ID NO:1 which renders the strain avirulent and able to protect fish against wild-type *Vibrio anguillarum*. The mutant strain disclosed in the instant specification contains an insertion in the *mugA* gene which is represented by SEQ ID NO:1. The specification that the *mugA* gene products enable the bacterium to better grow in mucus. The claimed mutant was selected on its inability to grow in mucus and its ability

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to protect against wild-type *Vibrio anguillarum* while not harming the host. The sequence set forth in SEQ ID NO:1 is critical to the invention in that it is needed in order to develop mutants which are avirulent and cannot grow in mucus and which can protect the subject against wild-type *Vibrio anguillarum*. Without the sequence set forth in SEQ ID NO:1, it would take undue experimentation for one of skill in the art to make a mutant with the properties specific to M93Sm D and which would have the ability to protect against wild-type *Vibrio anguillarum*.

Claim 30 does not even require there to be a mutation in the gene responsible for producing the *mugA* protein. Accordingly, it reads on mutants which have lost the ability to grow in mucous due to loss of pili or bacterium with entirely different mutations which render the bacterium incapable of functioning properly. The method of mutation, i.e., deletion or insertion, is not critical as long as the mutant possesses the desired properties because these techniques were routine in the art at the time the invention was made. However, the gene and the location of the mutation is a critical element and must be claimed. The specification does not identify any other *mugA* gene. As stated above, while the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The present invention is not enabled for mutants which do not set forth the specific mutation. The enablement in this case only sets forth *V.anguillarum* mutants which were obtained by making mutations to the *mugA* gene contained in SEQ ID NO:1 and therefore the written description is not commensurate in scope with the claims drawn to mutants comprising *any V.anguillarum* containing a mutation

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wherein the strain is incapable of growing in salmon intestinal mucous. The latter of which is recited in claim 30 does not require the strain to have a mutation in the *mugA* gene and reads on bacterium which contain other fatal mutations or problems with their pili. It would take undue experimentation for one of skill in the art to identify a random *V. anguillarum* mutant in nature which is incapable of growing in salmon intestinal mucous.

Status of claims

7. No claims are allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official

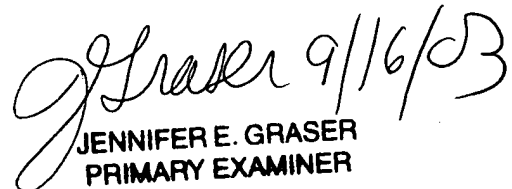
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Gazette, 1096 OG 30 (November 15,1989). The Group 1641 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (703) 308-1742. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

 9/16/03
JENNIFER E. GRASER
PRIMARY EXAMINER